GSK and Vir Biotechnology announce Joint Procurement Agreement with European Commission for COVID-19 treatment, sotrovimab

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GlaxoSmithKline plc and Vir Biotechnology, Inc. today announced they have signed a Joint Procurement Agreement with the European Commission to supply up to 220,000 doses of sotrovimab, an investigational single dose SARS-CoV-2 monoclonal antibody for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require oxygen supplementation and who are at risk of progressing to severe COVID-19. The Joint Procurement Agreement enables participating European Union (EU) Member States to quickly purchase sotrovimab, following local emergency authorisation or authorisation at the EU level, to treat high-risk patients with COVID-19 who may benefit from early treatment with sotrovimab.

This action follows the positive scientific opinion issued by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), under Article 5(3) of Regulation 726/2004, which can be considered by the national authorities in EU Member States when taking evidence-based decisions on the early use of the medicine prior to marketing authorisation. Sotrovimab is included in the European Commission's portfolio of promising candidate therapies as part of its COVID-19 Therapeutics Strategy. In addition, the documentation to support the forthcoming marketing authorisation application for sotrovimab is under rolling regulatory review with the EMA. In June, the companies announced confirmatory

full results for the Phase 3 COMET-ICE trial, which resulted in a 79% reduction (adjusted relative risk reduction) (p

George Katzourakis, Senior Vice President, Europe, GSK said:

> This agreement with the European Commission represents a crucial step forward for treating cases of COVID-19 in participating EU Member States, as it enables access to sotrovimab for high-risk patients who have contracted the virus. As the COVID-19 landscape continues to evolve and we meet new challenges – such as the Delta variant spreading across the globe – there remains an urgent need for treatment options to help those who do get sick to potentially avoid hospitalisation or death.

George Scangos, Ph.D., Chief Executive Officer of Vir, said:

> It remains abundantly clear that additional treatment options are needed to fully address the toll of this pandemic. This agreement recognises that monoclonal antibody treatments for those who become infected are essential, and we are pleased that European healthcare providers and their patients now have access to sotrovimab. Notably, the fact that sotrovimab was designed from the beginning to maintain activity against the evolution of this virus and has demonstrated, in vitro, its ability to maintain activity against the tested circulating variants of concern and interest, including Delta and Lambda, underscore its critical role in the fight against COVID-19.

Recognising the acute urgency of patient need across the world, the companies are engaging with governments and procurement bodies to make sotrovimab available to support the pandemic response.

GSK and Vir have secured supply agreements with multiple governments around the world and will continue those efforts as the pandemic continues to evolve. In May 2021, sotrovimab was granted Emergency Use Authorisation(EUA) by the U.S. Food and Drug Administration (FDA) for the treatment of mild-to moderate COVID-19 in high risk patients. GSK and Vir have announced plans to submit a Biologics License Application (BLA) to the U.S. FDA in the second half of 2021. Sotrovimab has also been authorised for emergency use in Bahrain, Kuwait, Qatar, Singapore and United Arab Emirates.

GSK and Vir are committed to ongoing evaluation of sotrovimab as the COVID-19 landscape continues to evolve at different rates across the globe and new variants of concern and interest emerge. Updated in vitro data, published in bioRxiv, demonstrate that sotrovimab retains activity against currently circulating variants of concern and interest of the SARS-CoV-2 virus including Alpha (B.1.1.7), Beta (B.1.351), Delta (B.1.617.2), Epsilon (B.1.427/B.1.429), Gamma (P.1), Iota (B.1.526), Kappa (B.1.617.1), and Lambda (C.37), as well as new variants from Bristol (B.1.1.7+E484K) and Cameroon (B.1.619), which encodes both N440K and E484K mutations that may lead to reduced activity for other neutralising monoclonal antibodies against the SARS-CoV-2 virus. GSK and Vir are continuing to evaluate the ability of sotrovimab to maintain activity against new and emerging variants through in vitro studies. The clinical impact of these in vitro variant data is not yet known.

The multi-centre, double-blind, placebo-controlled, Phase 3 COMET-ICE trial investigated intravenous

(IV) infusion of sotrovimab in adults with mild-to-moderate COVID-19 at high risk of progression to severe disease. In March 2021, an Independent Data Monitoring Committee recommended that the COMET-ICE trial be stopped for enrolment due to evidence of profound efficacy and is continuing to follow trial participants for 24 weeks. Interim data results have been shared with regulatory authorities and formed the basis of the positive scientific opinion reached by the EMA’s CHMP, under Article 5(3) of Regulation 726/2004.

This ongoing trial evaluated the safety and efficacy of a single IV infusion of sotrovimab (500 mg) or placebo in non-hospitalised participants globally. The primary efficacy endpoint was the proportion of patients who have progression of COVID-19 as defined by the need for hospitalisation for greater than 24 hours for acute management of any illness or death from any cause.

The final COMET-ICE trial results in the full study population of 1,057 participants demonstrated a 79% reduction (adjusted relative risk reduction) (p24 hours for acute management of any illness or death from any cause at Day 29 was six patients in the sotrovimab arm (1%), versus 30 patients in the placebo arm (6%). In the sotrovimab arm, it is possible that half of those patients who were hospitalised

were for reasons other than progression of COVID-19 (e.g., small bowel obstruction, lung cancer and diabetic foot ulcer); this was not the case for patients in the placebo arm.

In the safety analysis, 1,037 participants were followed through at least 29 days. The most common adverse events observed in the sotrovimab treatment group in COMET-ICE were rash (1%) and diarrhoea (2%), all of which were Grade 1 (mild) or Grade 2 (moderate). No other treatment-emergent adverse events were reported at a higher rate with sotrovimab compared to placebo.

About the Sotrovimab Clinical Development Programme

In addition to the COMET-ICE trial, the full COMET clinical development programme for sotrovimab includes:

COMET-PEAK, a pharmacokinetic trial in outpatients with mild-to-moderate COVID-19 investigating intramuscular (IM) administration of sotrovimab, is near completion and initial data are expected in the second half of 2021.

COMET-TAIL has been initiated. This is a Phase 3 trial evaluating the role of IM-administered sotrovimab for the early treatment of mild-to-moderate COVID-19 in high-risk non-hospitalised adult and paediatric patients (12 years of age and older). Data are anticipated in the first half of 2022.

The companies also plan to investigate the use of sotrovimab in uninfected immunocompromised adults to determine whether sotrovimab can prevent symptomatic COVID-19 infection.

Sotrovimab is an investigational SARS-CoV-2 monoclonal antibody. Preclinical data suggest it has the potential to both block viral entry into healthy cells and clear infected cells. The antibody binds to an epitope on SARS-CoV-2 that is shared with SARS-CoV-1 (the virus that causes SARS), indicating that the epitope is highly conserved, which may make it more difficult for resistance to develop. Sotrovimab, which incorporates Xencor's Xtend™ technology, also has been designed to achieve high concentration in the lungs to ensure optimal penetration into airway tissues affected by SARS-CoV-2 and to have an extended half-life.

Important Information about Sotrovimab in Europe

For more information on the EMA positive scientific opinion, please review the EU Conditions of Use.

All side effects have been mild or moderate. Healthcare professionals should look out for side effects and take appropriate action.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system listed in Appendix V.

Sotrovimab in the United States

Healthcare providers in the U.S. should review the Fact Sheets for information on the authorized use of sotrovimab and mandatory requirements of the EUA.

Sotrovimab has been authorized by the U.S. FDA for the emergency use described below. Sotrovimab is not FDA-approved for this use.

Sotrovimab is authorized only for the duration of the declaration that circumstances exist justifying the emergency use of sotrovimab under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product sotrovimab for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

Limitations of Authorized Use

Sotrovimab is not authorized for use in patients:

- who are hospitalized due to COVID-19, OR

- who require oxygen therapy due to COVID-19, OR

- who require an increase in baseline oxygen flow rate due to COVID-19 (in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity).

Benefit of treatment with sotrovimab has not been observed in patients hospitalized due to COVID-19. SARS-CoV-2 monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.

Please see the FDA Letter of Authorization, full Fact Sheet for Healthcare Providers, and full Fact Sheet for Patients, Parents, and Caregivers.

About the Vir and GSK Collaboration

In April 2020, Vir and GSK entered into a collaboration to research and develop solutions for coronaviruses, including SARS-CoV-2, the virus that causes COVID-19. The collaboration uses Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies that could be used as therapeutic or preventive options to help address the current COVID-19 pandemic and future outbreaks. The companies will leverage GSK's expertise in functional genomics and combine their capabilities in CRISPR screening and artificial intelligence to identify anti-coronavirus compounds that target cellular host genes. They will also apply their combined expertise to research SARS-CoV-2 and other coronavirus vaccines.

GSK Commitment to Tackling COVID-19

GSK's response to COVID-19 has been one of the broadest in the industry, with three potential treatments in addition to our vaccine candidates in development with partner organisations. GSK is collaborating with several organisations on COVID-19 vaccines by providing access to our adjuvant technology. In addition to our work with Medicago, we recently announced positive Phase 2 data from our collaboration with Sanofi to develop an adjuvanted, protein-based vaccine candidate and started a Phase 3 trial in Q2. An earlier stage collaboration with SK Bioscience is also ongoing. SK Bioscience receives funding from CEPI and the Bill and Melinda Gates Foundation to develop differentiated, affordable COVID-19 vaccines for supply globally through the COVAX facility. The use of an adjuvant

can be of particular importance in a pandemic since it may reduce the amount of vaccine protein required per dose, allowing more vaccine doses to be produced and contributing to protecting more people.

GSK is also working with mRNA specialist, CureVac, to jointly develop next generation, multi-valent mRNA vaccines for COVID-19 with the potential to address multiple emerging variants in one vaccine. GSK will also support manufacturing of up to 100m doses of CureVac's first generation COVID-19 vaccine. GSK is also providing manufacturing support for up to 60m doses of Novavax' COVID-19 vaccine in the UK.

GSK is also exploring potential therapeutic or treatment options for COVID-19 patients. We are also assessing whether an investigational monoclonal antibody, otilimab, can help severely ill COVID-19 patients aged over 70 who experience an overreaction of their immune system.

Vir's Commitment to COVID-19

Vir was founded with the mission of addressing the world's most serious infectious diseases. In 2020, Vir responded rapidly to the COVID-19 pandemic by leveraging our unique scientific insights and industry leading antibody platform to explore multiple monoclonal antibodies as potential therapeutic or preventive options for COVID-19. Sotrovimab is the first SARS-CoV-2-targeting antibody Vir advanced into the clinic. It was carefully selected for its demonstrated promise in preclinical research, including an anticipated high barrier to resistance and potential ability to both block the virus from entering healthy cells and clear infected cells. Vir is continuing to pursue novel therapeutic and prophylactic solutions to combat SARSCoV-2 and future coronavirus pandemics, both independently and in collaboration with its partners.

GSK is a science-led global healthcare company. For further information please visit www.gsk.com/aboutus.

Vir Biotechnology is a clinical-stage immunology company focused on combining immunologic insights with cutting-edge technologies to treat and prevent serious infectious diseases. Vir has assembled four technology platforms that are designed to stimulate and enhance the immune system by exploiting critical observations of natural immune processes. Its current development pipeline consists of product candidates targeting COVID-19, hepatitis B virus, influenza A and

human immunodeficiency virus. For more information, please visit www.vir.bio.

GSK Cautionary Statement Regarding Forward-Looking Statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in the Company's Annual Report on Form 20-F for 2020 and any impacts of the COVID-19 pandemic.

Vir Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “plan,” “potential,” “aim,” “promising” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. These forward-looking statements are based on Vir’s expectations and assumptions as of the date of this press release. Forward-looking statements contained in this press release include, but are not limited to, statements regarding the ability of sotrovimab to treat and/or prevent COVID-19, our collaboration with GSK, an agreement with the European Commission to supply sotrovimab and other potential supply agreements, the clinical development program for sotrovimab, and the ability of sotrovimab to maintain activity against circulating variants of concern. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, challenges in the treatment of hospitalized patients, difficulties in collaborating with other companies or government agencies, challenges in accessing manufacturing capacity, successful development and/or commercialization of alternative product candidates by Vir’s competitors, changes in expected or existing competition, delays in or disruptions to Vir’s business or clinical trials due to the COVID-19 pandemic, geopolitical changes or other external factors, and unexpected litigation or other disputes. Other factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir’s filings with the U.S. Securities

and Exchange Commission, including the section titled “Risk Factors” contained therein. Except as required by law, Vir assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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